

109TH CONGRESS
2D SESSION

S. 2564

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 6, 2006

Mr. BURR (for himself, Mr. FRIST, Mr. ENZI, Mr. GREGG, Mr. ALEXANDER, and Mrs. DOLE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To prepare and strengthen the biodefenses of the United States against deliberate, accidental, and natural outbreaks of illness, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Biodefense and Pan-
5 demic Vaccine and Drug Development Act of 2006”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Biomedical Advanced Research and Development Authority; National
Biodefense Science Board.

- Sec. 4. Clarification of countermeasures covered by Project BioShield.
- Sec. 5. Orphan drug market exclusivity for countermeasure products.
- Sec. 6. Technical assistance.
- Sec. 7. Collaboration and coordination.
- Sec. 8. Procurement.
- Sec. 9. Rule of construction.

1 **SEC. 3. BIOMEDICAL ADVANCED RESEARCH AND DEVELOP-**
 2 **MENT AUTHORITY; NATIONAL BIODEFENSE**
 3 **SCIENCE BOARD.**

4 (a) IN GENERAL.—Title III of the Public Health
 5 Service Act (42 U.S.C. 241 et seq.) is amended by insert-
 6 ing after section 319K the following:

7 **“SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DE-**
 8 **VELOPMENT AUTHORITY.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) BARDA.—The term ‘BARDA’ means the
 11 Biomedical Advanced Research and Development
 12 Authority.

13 “(2) FUND.—The term ‘Fund’ means the Bio-
 14 defense Medical Countermeasure Development Fund
 15 established under subsection (d).

16 “(3) OTHER TRANSACTIONS.—The term ‘other
 17 transactions’ means transactions, other than pro-
 18 curement contracts, grants, and cooperative agree-
 19 ments, such as the Secretary of Defense may enter
 20 into under section 2371 of title 10, United States
 21 Code.

1 “(4) QUALIFIED COUNTERMEASURE.—The term
2 ‘qualified countermeasure’ has the meaning given
3 such term in section 319F–1.

4 “(5) QUALIFIED PANDEMIC OR EPIDEMIC PROD-
5 UCT.—The term ‘qualified pandemic or epidemic
6 product’ has the meaning given the term in section
7 319F–3.

8 “(6) ADVANCED RESEARCH AND DEVELOP-
9 MENT.—

10 “(A) IN GENERAL.—The term ‘advanced
11 research and development’ means, with respect
12 to a product that is or may become a qualified
13 countermeasure or a qualified pandemic or epi-
14 demic product, activities that predominantly—

15 “(i) are conducted after basic research
16 and preclinical development of the product;
17 and

18 “(ii) are related to manufacturing the
19 product on a commercial scale and in a
20 form that satisfies the regulatory require-
21 ments under the Federal Food, Drug, and
22 Cosmetic Act or under section 351 of this
23 Act.

24 “(B) ACTIVITIES INCLUDED.—The term
25 under subparagraph (A) includes—

1 “(i) testing of the product to deter-
2 mine whether the product may be ap-
3 proved, cleared, or licensed under the Fed-
4 eral Food, Drug, and Cosmetic Act or
5 under section 351 of this Act for a use
6 that is or may be the basis for such prod-
7 uct becoming a qualified countermeasure
8 or qualified pandemic or epidemic product,
9 or to help obtain such approval, clearance,
10 or license;

11 “(ii) design and development of tests
12 or models, including animal models, for
13 such testing;

14 “(iii) activities to facilitate manufac-
15 ture of the product on a commercial scale
16 with consistently high quality, as well as to
17 improve and make available new tech-
18 nologies to increase manufacturing surge
19 capacity;

20 “(iv) activities to improve the shelf-life
21 of the product or technologies for admin-
22 istering the product; and

23 “(v) such other activities as are part
24 of the advanced stages of testing, refine-
25 ment, improvement, or preparation of the

1 product for such use and as are specified
2 by the Secretary.

3 “(7) SECURITY COUNTERMEASURE.—The term
4 ‘security countermeasure’ has the meaning given
5 such term in section 319F–2.

6 “(8) RESEARCH TOOL.—The term ‘research
7 tool’ means a device, technology, biological material
8 (including a cell line or an antibody), reagent, ani-
9 mal model, computer system, computer software, or
10 analytical technique that is developed to assist in the
11 discovery, development, or manufacture of qualified
12 countermeasures or qualified pandemic or epidemic
13 products.

14 “(9) PROGRAM MANAGER.—The term ‘program
15 manager’ means an individual appointed to carry out
16 functions under this section and authorized to pro-
17 vide project oversight and management of strategic
18 initiatives.

19 “(10) PERSON.—The term ‘person’ includes an
20 individual, partnership, corporation, association, en-
21 tity, or public or private corporation, and a Federal,
22 State, or local government agency or department.

23 “(b) STRATEGIC PLAN FOR COUNTERMEASURE RE-
24 SEARCH, DEVELOPMENT, AND PROCUREMENT.—

1 “(1) IN GENERAL.—Not later than 6 months
2 after the date of enactment of the Biodefense and
3 Pandemic Vaccine and Drug Development Act of
4 2006, the Secretary shall develop and make public a
5 strategic plan to integrate biodefense and emerging
6 infectious disease requirements with the advanced
7 research and development, strategic initiatives for
8 innovation, and the procurement of qualified coun-
9 termeasures and qualified pandemic or epidemic
10 products.

11 “(2) CONTENT.—The strategic plan under
12 paragraph (1) shall guide—

13 “(A) research and development, conducted
14 or supported by the Department of Health and
15 Human Services, of qualified countermeasures
16 and qualified pandemic or epidemic products
17 against possible biological, chemical, radio-
18 logical, and nuclear agents and to emerging in-
19 fectious diseases;

20 “(B) innovation in technologies that may
21 assist advanced research and development of
22 qualified countermeasures and qualified pan-
23 demic or epidemic products (such research and
24 development referred to in this section as ‘coun-

1 termeasure and product advanced research and
2 development’); and

3 “(C) procurement of such qualified coun-
4 termesures and qualified pandemic or epidemic
5 products by such Department.

6 “(c) BIOMEDICAL ADVANCED RESEARCH AND DE-
7 VELOPMENT AUTHORITY.—

8 “(1) ESTABLISHMENT.—There is established
9 within the Department of Health and Human Serv-
10 ices the Biomedical Advanced Research and Develop-
11 ment Authority.

12 “(2) IN GENERAL.—Based upon the strategic
13 plan described in subsection (b), the Secretary shall
14 coordinate and oversee the acceleration of counter-
15 measure and product advanced research and devel-
16 opment by—

17 “(A) facilitating collaboration among the
18 Department of Health and Human Services,
19 other Federal agencies, relevant industries, aca-
20 demia, and other persons, with respect to such
21 advanced research and development;

22 “(B) promoting countermeasure and prod-
23 uct advanced research and development;

24 “(C) facilitating contacts between inter-
25 ested persons and the offices or employees au-

1 thorized by the Secretary to advise such persons
2 regarding requirements under the Federal
3 Food, Drug, and Cosmetic Act and under sec-
4 tion 351 of this Act; and

5 “(D) promoting innovation to reduce the
6 time and cost of countermeasure and product
7 advanced research and development.

8 “(3) DIRECTOR.—The BARDA shall be headed
9 by a Director (referred to in this section as the ‘Di-
10 rector’) who shall be appointed by the Secretary and
11 to whom the Secretary shall delegate such functions
12 and authorities as necessary to implement this sec-
13 tion.

14 “(4) DUTIES.—

15 “(A) COLLABORATION.—To carry out the
16 purpose described in paragraph (2)(A), the Sec-
17 retary shall—

18 “(i) facilitate and increase the expedi-
19 tious and direct communication between
20 the Department of Health and Human
21 Services and relevant persons with respect
22 to countermeasure and product advanced
23 research and development, including by—

24 “(I) facilitating such communica-
25 tion regarding the processes for pro-

1 curing such advanced research and
2 development with respect to qualified
3 countermeasures and qualified pan-
4 demic or epidemic products of inter-
5 est; and

6 “(II) soliciting information about
7 and data from research on potential
8 qualified countermeasures and quali-
9 fied pandemic or epidemic products
10 and related technologies;

11 “(ii) at least annually—

12 “(I) convene meetings with rep-
13 resentatives from relevant industries,
14 academia, other Federal agencies,
15 international agencies as appropriate,
16 and other interested persons;

17 “(II) sponsor opportunities to
18 demonstrate the operation and effec-
19 tiveness of relevant biodefense coun-
20 termeasure technologies; and

21 “(III) convene such working
22 groups on countermeasure and prod-
23 uct advanced research and develop-
24 ment as the Secretary may determine

1 are necessary to carry out this sec-
2 tion; and

3 “(iii) carry out the activities described
4 in section 7 of the Biodefense and Pan-
5 demic Vaccine and Drug Development Act
6 of 2006.

7 “(B) SUPPORT ADVANCED RESEARCH AND
8 DEVELOPMENT.—To carry out the purpose de-
9 scribed in paragraph (2)(B), the Secretary
10 shall—

11 “(i) conduct ongoing searches for, and
12 support calls for, potential qualified coun-
13 termeasures and qualified pandemic or epi-
14 demic products;

15 “(ii) direct and coordinate the coun-
16 termeasure and product advanced research
17 and development activities of the Depart-
18 ment of Health and Human Services;

19 “(iii) establish strategic initiatives to
20 accelerate countermeasure and product ad-
21 vanced research and development and in-
22 novation in such areas as the Secretary
23 may identify as priority unmet need areas;
24 and

1 “(iv) award contracts, grants, cooper-
2 ative agreements, and enter into other
3 transactions, for countermeasure and prod-
4 uct advanced research and development.

5 “(C) FACILITATING ADVICE.—To carry out
6 the purpose described in paragraph (2)(C) the
7 Secretary shall—

8 “(i) connect interested persons with
9 the offices or employees authorized by the
10 Secretary to advise such persons regarding
11 the regulatory requirements under the
12 Federal Food, Drug, and Cosmetic Act
13 and under section 351 of this Act related
14 to the approval, clearance, or licensure of
15 qualified countermeasures or qualified pan-
16 demic or epidemic products; and

17 “(ii) ensure that, with respect to per-
18 sons performing countermeasure and prod-
19 uct advanced research and development
20 funded under this section, such offices or
21 employees provide such advice in a manner
22 that is ongoing and that is otherwise des-
23 ignated to facilitate expeditious develop-
24 ment of qualified countermeasures and
25 qualified pandemic or epidemic products

1 that may achieve such approval, clearance,
2 or licensure.

3 “(D) SUPPORTING INNOVATION.—To carry
4 out the purpose described in paragraph (2)(D),
5 the Secretary may award contracts, grants, and
6 cooperative agreements, or enter into other
7 transactions, such as prize payments, to pro-
8 mote—

9 “(i) innovation in technologies that
10 may assist countermeasure and product
11 advanced research and development;

12 “(ii) research on and development of
13 research tools and other devices and tech-
14 nologies; and

15 “(iii) research to promote strategic
16 initiatives, such as rapid diagnostics, broad
17 spectrum antimicrobials, and vaccine man-
18 ufacturing technologies.

19 “(5) TRANSACTION AUTHORITIES.—

20 “(A) OTHER TRANSACTIONS.—In carrying
21 out the functions under subparagraph (B) or
22 (D) of paragraph (4), the Secretary shall have
23 authority to enter into other transactions for
24 countermeasure and product advanced research
25 and development.

1 “(B) EXPEDITED AUTHORITIES.—

2 “(i) IN GENERAL.—In awarding con-
3 tracts, grants, and cooperative agreements,
4 and in entering into other transactions
5 under subparagraph (B) or (D) of para-
6 graph (4), the Secretary shall have the ex-
7 pedited procurement authorities, the au-
8 thority to expedite peer review, and the au-
9 thority for personal services contracts, sup-
10 plied by subsections (b), (c), and (d) of
11 section 319F–1.

12 “(ii) APPLICATION OF PROVISIONS.—
13 Provisions in such section 319F–1 that
14 apply to such authorities and that require
15 institution of internal controls, limit re-
16 view, provide for Federal Tort Claims Act
17 coverage of personal services contractors,
18 and commit decisions to the discretion of
19 the Secretary shall apply to the authorities
20 as exercised pursuant to this paragraph.

21 “(iii) AUTHORITY TO LIMIT COMPETI-
22 TION.—For purposes of applying section
23 319F–1(b)(1)(D) to this paragraph, the
24 phrase ‘BioShield Program under the
25 Project BioShield Act of 2004’ shall be

1 deemed to mean the countermeasure and
2 product advanced research and develop-
3 ment program under this section.

4 “(iv) AVAILABILITY OF DATA.—The
5 Secretary shall require that, as a condition
6 of being awarded a contract, grant, cooper-
7 ative agreement, or other transaction
8 under subparagraph (B) or (D) of para-
9 graph (4), a person make available to the
10 Secretary on an ongoing basis, and submit
11 upon request to the Secretary, all data re-
12 lated to or resulting from countermeasure
13 and product advanced research and devel-
14 opment carried out pursuant to this sec-
15 tion.

16 “(C) ADVANCE PAYMENTS; ADVER-
17 TISING.—The authority of the Secretary to
18 enter into contracts under this section shall not
19 be limited by section 3324(a) of title 31, United
20 States Code, or by section 3709 of the Revised
21 Statutes of the United States (41 U.S.C. 5).

22 “(D) MILESTONE-BASED PAYMENTS AL-
23 LOWED.—In awarding contracts, grants, and
24 cooperative agreements, and in entering into
25 other transactions, under this section, the Sec-

1 retary may use milestone-based awards and
2 payments.

3 “(E) FOREIGN NATIONALS ELIGIBLE.—

4 The Secretary may under this section award
5 contracts, grants, and cooperative agreements
6 to, and may enter into other transactions with,
7 highly qualified foreign national persons outside
8 the United States, alone or in collaboration with
9 American participants, when such transactions
10 may inure to the benefit of the American peo-
11 ple.

12 “(F) ESTABLISHMENT OF RESEARCH CEN-

13 TERS.—The Secretary may establish one or
14 more federally-funded research and development
15 centers, or university-affiliated research centers
16 in accordance with section 303(c)(3) of the
17 Federal Property and Administrative Services
18 Act of 1949 (41 U.S.C. 253(c)(3)).

19 “(6) VULNERABLE POPULATIONS.—In carrying

20 out the functions under this section, the Secretary
21 may give priority to the advanced research and de-
22 velopment of qualified countermeasures and qualified
23 pandemic or epidemic products that are likely to be
24 safe and effective with respect to children, pregnant
25 women, and other vulnerable populations.

1 “(7) PERSONNEL AUTHORITIES.—

2 “(A) SPECIALLY QUALIFIED SCIENTIFIC
3 AND PROFESSIONAL PERSONNEL.—In addition
4 to any other personnel authorities, the Sec-
5 retary may—

6 “(i) without regard to those provisions
7 of title 5, United States Code, governing
8 appointments in the competitive service,
9 appoint highly qualified individuals to sci-
10 entific or professional positions in
11 BARDA, such as program managers, to
12 carry out this section; and

13 “(ii) compensate them in the same
14 manner in which individuals appointed
15 under section 9903 of such title are com-
16 pensated, without regard to the provisions
17 of chapter 51 and subchapter III of chap-
18 ter 53 of such title relating to classification
19 and General Schedule pay rates.

20 “(B) SPECIAL CONSULTANTS.—In carrying
21 out this section, the Secretary may—

22 “(i) appoint special consultants pursu-
23 ant to section 207(f); and

24 “(ii) accept voluntary and uncompen-
25 sated services.

1 “(d) FUND.—

2 “(1) ESTABLISHMENT.—There is established
3 the Biodefense Medical Countermeasure Develop-
4 ment Fund, which shall be available to carry out this
5 section.

6 “(2) FUNDS.—

7 “(A) FIRST FISCAL YEAR.—

8 “(i) AUTHORIZATION AND APPROPRIA-
9 TION.—There are authorized to be appro-
10 priated and there are appropriated to the
11 Fund \$340,000,000 to carry out this sec-
12 tion for fiscal year 2007. Such funds shall
13 remain available until expended.

14 “(ii) AUTHORIZATION OF APPROPRIA-
15 TIONS.—There are authorized to be appro-
16 priated, in addition to the amounts appro-
17 priated under clause (i), \$160,000,000 to
18 carry out this section for fiscal year 2007.
19 Such funds shall remain available until ex-
20 pended.

21 “(B) SUBSEQUENT FISCAL YEARS.—

22 “(i) IN GENERAL.—There are author-
23 ized to be appropriated to carry out this
24 section—

1 “(I) \$500,000,000 for fiscal year
2 2008; and

3 “(II) such sums as may be nec-
4 essary for fiscal years 2009 through
5 2012.

6 “(ii) AVAILABILITY OF FUNDS.—Such
7 sums authorized under clause (i) shall re-
8 main available until expended.

9 “(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—
10 “(1) DISCLOSURE.—

11 “(A) IN GENERAL.—The Secretary shall
12 withhold from disclosure under section 552 of
13 title 5, United States Code, specific technical
14 data or scientific information that is created or
15 obtained during the countermeasure and prod-
16 uct advanced research and development funded
17 by the Secretary that reveal vulnerabilities of
18 existing medical or public health defenses
19 against biological, chemical, nuclear, or radio-
20 logical threats. Such information shall be
21 deemed to be information described in section
22 552(b)(3) of title 5, United States Code.

23 “(B) OVERSIGHT.—Information subject to
24 nondisclosure under subparagraph (A) shall be
25 reviewed by the Secretary every 5 years to de-

1 terminate the relevance or necessity of continued
2 nondisclosure.

3 “(2) FEDERAL ADVISORY COMMITTEE ACT.—
4 Section 14 of the Federal Advisory Committee Act
5 (5 U.S.C. App.) shall not apply to a working group
6 of BARDA or to the National Biodefense Science
7 Board under section 319M.

8 **“SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND**
9 **WORKING GROUPS.**

10 “(a) IN GENERAL.—

11 “(1) ESTABLISHMENT AND FUNCTION.—The
12 Secretary shall establish the National Biodefense
13 Science Board (referred to in this section as the
14 ‘Board’) to provide expert advice and guidance to
15 the Secretary on scientific, technical and other mat-
16 ters of special interest to the Department of Health
17 and Human Services regarding current and future
18 chemical, biological, nuclear, and radiological agents,
19 whether naturally occurring, accidental, or delib-
20 erate.

21 “(2) MEMBERSHIP.—The membership of the
22 Board shall be comprised of individuals who rep-
23 resent the Nation’s preeminent scientific, public
24 health, and medical experts, as follows—

1 “(A) such Federal officials as the Sec-
 2 retary may determine are necessary to support
 3 the functions of the Board;

4 “(B) four individuals representing the
 5 pharmaceutical, biotechnology, and device in-
 6 dustries;

7 “(C) four individuals representing aca-
 8 demia; and

9 “(D) five other members as determined ap-
 10 propriate by the Secretary.

11 “(3) TERM OF APPOINTMENT.—A member of
 12 the Board described in subparagraph (B), (C), or
 13 (D) of paragraph (2) shall serve for a term of 3
 14 years, except that the Secretary may adjust the
 15 terms of the initial Board appointees in order to
 16 provide for a staggered term of appointment for all
 17 members.

18 “(4) CONSECUTIVE APPOINTMENTS; MAXIMUM
 19 TERMS.—A member may be appointed to serve not
 20 more than 3 terms on the Board and may serve not
 21 more than 2 consecutive terms.

22 “(5) DUTIES.—The Board shall—

23 “(A) advise the Secretary on current and
 24 future trends, challenges, and opportunities pre-
 25 sented by advances in biological and life

1 sciences, biotechnology, and genetic engineering
2 with respect to threats posed by naturally oc-
3 ccurring infectious diseases and chemical, bio-
4 logical, radiological, and nuclear agents;

5 “(B) at the request of the Secretary, re-
6 view and consider any information and findings
7 received from the working groups established
8 under subsection (b); and

9 “(C) at the request of the Secretary, pro-
10 vide recommendations and findings for ex-
11 panded, intensified, and coordinated biodefense
12 research and development activities.

13 “(6) MEETINGS.—

14 “(A) INITIAL MEETING.—Not later than
15 one year after the date of enactment of the Bio-
16 defense and Pandemic Vaccine and Drug Devel-
17 opment Act of 2006, the Secretary shall hold
18 the first meeting of the Board.

19 “(B) SUBSEQUENT MEETINGS.—The
20 Board shall meet at the call of the Secretary,
21 but in no case less than twice annually.

22 “(7) VACANCIES.—Any vacancy in the Board
23 shall not affect its powers, but shall be filled in the
24 same manner as the original appointment.

1 “(8) CHAIRPERSON.—The Secretary shall ap-
2 point a chairperson from among the members of the
3 Board.

4 “(9) POWERS.—

5 “(A) HEARINGS.—The Board may hold
6 such hearings, sit and act at such times and
7 places, take such testimony, and receive such
8 evidence as the Board considers advisable to
9 carry out this subsection.

10 “(B) POSTAL SERVICES.—The Board may
11 use the United States mails in the same man-
12 ner and under the same conditions as other de-
13 partments and agencies of the Federal Govern-
14 ment.

15 “(10) PERSONNEL.—

16 “(A) EMPLOYEES OF THE FEDERAL GOV-
17 ERNMENT.—A member of the Board that is an
18 employee of the Federal Government may not
19 receive additional pay, allowances, or benefits
20 by reason of the member’s service on the
21 Board.

22 “(B) OTHER MEMBERS.—A member of the
23 Board that is not an employee of the Federal
24 Government may be compensated at a rate not
25 to exceed the daily equivalent of the annual rate

1 of basic pay prescribed for level IV of the Exec-
 2 utive Schedule under section 5315 of title 5,
 3 United States Code, for each day (including
 4 travel time) during which the member is en-
 5 gaged in the actual performance of duties as a
 6 member of the Board.

7 “(C) TRAVEL EXPENSES.—Each member
 8 of the Board shall receive travel expenses, in-
 9 cluding per diem in lieu of subsistence, in ac-
 10 cordance with applicable provisions under sub-
 11 chapter I of chapter 57 of title 5, United States
 12 Code.

13 “(D) DETAIL OF GOVERNMENT EMPLOY-
 14 EES.—Any Federal Government employee may
 15 be detailed to the Board with the approval for
 16 the contributing agency without reimbursement,
 17 and such detail shall be without interruption or
 18 loss of civil service status or privilege.

19 “(b) OTHER WORKING GROUPS.—The Secretary may
 20 establish a working group of experts, or may use an exist-
 21 ing working group or advisory committee, to—

22 “(1) identify innovative research with the po-
 23 tential to be developed as a qualified countermeasure
 24 or a qualified pandemic or epidemic product;

1 “(2) identify accepted animal models for par-
2 ticular diseases and conditions associated with any
3 biological, chemical, radiological, or nuclear agent,
4 any toxin, or any potential pandemic infectious dis-
5 ease, and identify strategies to accelerate animal
6 model and research tool development and validation;
7 and

8 “(3) obtain advice regarding supporting and fa-
9 cilitating advanced research and development related
10 to qualified countermeasures and qualified pandemic
11 or epidemic products that are likely to be safe and
12 effective with respect to children, pregnant women,
13 and other vulnerable populations, and other issues
14 regarding activities under this section that affect
15 such populations.

16 “(c) DEFINITIONS.—Any term that is defined in sec-
17 tion 319L and that is used in this section shall have the
18 same meaning in this section as such term is given in sec-
19 tion 319L.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated \$1,000,000 to carry out
22 this section for fiscal year 2007 and each fiscal year there-
23 after.”.

24 (b) OFFSET OF FUNDING.—The amount appro-
25 priated under the subheading “Biodefense Counter-

1 measures” under the heading “Emergency Preparedness
 2 and Response” in title III of the Department of Homeland
 3 Security Appropriations Act, 2004 (Public Law 108–90)
 4 shall be decreased by \$340,000,000.

5 **SEC. 4. CLARIFICATION OF COUNTERMEASURES COVERED**
 6 **BY PROJECT BIOSHIELD.**

7 (a) **QUALIFIED COUNTERMEASURE.**—Section 319F–
 8 1(a) of the Public Health Service Act (42 U.S.C. 247d–
 9 6a(a)) is amended by striking paragraph (2) and inserting
 10 the following:

11 “(2) **DEFINITIONS.**—In this section:

12 “(A) **QUALIFIED COUNTERMEASURE.**—The
 13 term ‘qualified countermeasure’ means a drug
 14 (as that term is defined by section 201(g)(1) of
 15 the Federal Food, Drug, and Cosmetic Act (21
 16 U.S.C. 321(g)(1))), biological product (as that
 17 term is defined by section 351(i) of this Act (42
 18 U.S.C. 262(i))), or device (as that term is de-
 19 fined by section 201(h) of the Federal Food,
 20 Drug, and Cosmetic Act (21 U.S.C. 321(h))),
 21 that the Secretary determines to be a priority
 22 (consistent with sections 302(2) and 304(a) of
 23 the Homeland Security Act of 2002) to—

24 “(i) diagnose, mitigate, prevent, or
 25 treat harm from any biological agent (in-

cluding organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

“(ii) diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph.

“(B) INFECTIOUS DISEASE.—The term ‘infectious disease’ means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.”.

(b) SECURITY COUNTERMEASURE.—Section 319F–2(c)(1)(B) is amended by striking “treat, identify, or prevent” each place it appears and inserting “diagnose, mitigate, prevent, or treat”.

(c) LIMITATION ON USE OF FUNDS.—Section 510(a) of the Homeland Security Act of 2002 (6 U.S.C. 320(a)) is amended by adding at the end the following: “None of the funds made available under this subsection shall be

1 used to procure countermeasures to diagnose, mitigate,
 2 prevent, or treat harm resulting from any naturally occur-
 3 ring infectious disease.”.

4 **SEC. 5. ORPHAN DRUG MARKET EXCLUSIVITY FOR COUN-**
 5 **TERMEASURE PRODUCTS.**

6 (a) IN GENERAL.—Section 527 of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended
 8 by adding at the end the following:

9 “(c) MARKET EXCLUSIVITIES FOR COUNTER-
 10 MEASURES, ANTIBIOTICS, AND ANTIINFECTIVES.—

11 “(1) IN GENERAL.—Except as provided in para-
 12 graph (2), with respect to a drug that is designated
 13 under section 526 for a rare disease or condition,
 14 the period referred to in this section is deemed to be
 15 10 years in lieu of 7 years if—

16 “(A) such rare disease or condition is di-
 17 rectly caused by a—

18 “(i)(I) biological agent (including an
 19 organism that causes infectious disease);

20 “(II) toxin; or

21 “(III) chemical, radiological, or nu-
 22 clear agent; and

23 “(ii) such biological agent (including
 24 an organism that causes an infectious dis-
 25 ease), toxin, or chemical, radiological or

1 nuclear agent, is identified as a material
2 threat under subsection (c)(2)(A)(ii) of
3 section 319F–2 of the Public Health Serv-
4 ice Act;

5 “(B) such drug is determined by the Sec-
6 retary to be a security countermeasure under
7 subsection (c)(1)(B) of such section 319F–2
8 with respect to such agent or toxin;

9 “(C) no active ingredient (including a salt
10 or ester of the active ingredient) of the drug
11 has been approved under an application under
12 section 505(b) prior to the submission of the re-
13 quest for designation of the new drug under
14 section 526; and

15 “(D) notice respecting the designation of a
16 drug under section 526 has been made available
17 to the public.

18 “(2) APPLICATION OF PROVISION.—Paragraph
19 (1) shall apply with respect to an antibiotic drug or
20 antiinfective drug designated under section 526 only
21 if—

22 “(A) no active ingredient (including a salt
23 or ester of the active ingredient) of such drug
24 has been approved as a feed or water additive
25 for an animal in the absence of any clinical sign

1 of disease in the animal for growth promotion,
2 feed efficiency, weight gain, routine disease pre-
3 vention, or other routine purpose;

4 “(B) no active ingredient (including a salt
5 or ester of the active ingredient) of such drug
6 has been approved for use in humans under
7 section 505 or approved for human use under
8 section 507 (as in effect prior to November 21,
9 1997) prior to the submission of the request for
10 designation of the new drug under section 526;

11 “(C) the Secretary has made a determina-
12 tion that—

13 “(i) such drug is not a member of a
14 class of antibiotics that is particularly
15 prone to creating antibiotic resistance;

16 “(ii) sufficient antibiotics do not al-
17 ready exist in the same class;

18 “(iii) such drug represents a signifi-
19 cant clinical improvement over other anti-
20 biotic drugs;

21 “(iv) such drug is for a serious or life-
22 threatening disease or conditions; and

23 “(v) such drug is for a counter-
24 measure use; and

1 “(D) notice respecting the designation of a
2 drug under section 526 has been made available
3 to the public.

4 “(3) RULE OF CONSTRUCTION.—With respect
5 to a drug to which this subsection applies, and which
6 is also approved for additional uses to which this
7 subsection does not apply, nothing in section
8 505(b)(2) or 505(j) shall prohibit the Secretary from
9 approving a drug under section 505(b)(2) or 505(j)
10 with different or additional labeling for the drug as
11 the Secretary deems necessary to ensure that the
12 drug is safe and effective for the uses to which this
13 subsection does not apply.

14 “(4) STUDY AND REPORT.—Not later than Jan-
15 uary 1, 2011, the Comptroller General of the United
16 States shall conduct a study and submit to Congress
17 a report concerning the effect of and activities under
18 this subsection. Such study and report shall examine
19 all relevant issues including—

20 “(A) the effectiveness of this subsection in
21 improving the availability of novel counter-
22 measures for procurement under section 319F–
23 2 of the Public Health Service Act;

24 “(B) the effectiveness of this subsection in
25 improving the availability of drugs that treat

1 serious or life threatening diseases or conditions
2 and offer significant clinical improvements;

3 “(C) the continued need for additional in-
4 centives to create more antibiotics and
5 antiinfectives;

6 “(D) the economic impact of the section on
7 taxpayers and consumers, including—

8 “(i) the economic value of additional
9 drugs provided for under this subsection,
10 including the impact of improved health
11 care and hospitalization times associated
12 with treatment of nosocomial infections;
13 and

14 “(ii) the economic cost of any delay in
15 the availability of lower cost generic drugs
16 on patients, the insured, and Federal and
17 private health plans;

18 “(E) the adequacy of limits under subpara-
19 graphs (A) and (B) of paragraph (2) to maxi-
20 mize the useful period during which antibiotic
21 drugs or antiinfective drugs remain therapeuti-
22 cally useful treatments; and

23 “(F) any recommendations for modifica-
24 tions to this subsection that the Comptroller de-
25 termines to be appropriate.

1 “(5) EFFECTIVE DATE.—This subsection shall
 2 apply only to products for which an applicant has
 3 applied for designation under section 526 after the
 4 date of enactment of the Biodefense and Pandemic
 5 Vaccine and Drug Development Act of 2006.

6 “(6) SUNSET.—This subsection shall not apply
 7 with respect to any designation of a drug under sec-
 8 tion 526 made by the Secretary on or after October
 9 1, 2011.”.

10 **SEC. 6. TECHNICAL ASSISTANCE.**

11 Subchapter E of chapter V of the Federal Food,
 12 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
 13 amended by adding at the end the following:

14 **“SEC. 565. TECHNICAL ASSISTANCE.**

15 “The Secretary, in consultation with the Commis-
 16 sioner of Food and Drugs, shall establish within the Food
 17 and Drug Administration a team of experts on manufac-
 18 turing and regulatory activities (including compliance with
 19 current Good Manufacturing Practice) to provide both off-
 20 site and on-site technical assistance to the manufacturers
 21 of qualified countermeasures (as defined in section 319F–
 22 1 of the Public Health Service Act), security counter-
 23 measures (as defined in section 319F–2 of such Act), or
 24 vaccines, at the request of such a manufacturer and at
 25 the discretion of the Secretary, if the Secretary determines

1 that a shortage or potential shortage may occur in the
 2 United States in the supply of such vaccines or counter-
 3 measures and that the provision of such assistance would
 4 be beneficial in helping alleviate or avert such shortage.”.

5 **SEC. 7. COLLABORATION AND COORDINATION.**

6 (a) LIMITED ANTITRUST EXEMPTION.—

7 (1) MEETINGS AND CONSULTATIONS TO DIS-
 8 CUSS SECURITY COUNTERMEASURES, QUALIFIED
 9 COUNTERMEASURES, OR QUALIFIED PANDEMIC OR
 10 EPIDEMIC PRODUCT DEVELOPMENT.—

11 (A) AUTHORITY TO CONDUCT MEETINGS
 12 AND CONSULTATIONS.—The Secretary of
 13 Health and Human Services (referred to in this
 14 subsection as the “Secretary”), in coordination
 15 with the Attorney General and the Secretary of
 16 Homeland Security, may conduct meetings and
 17 consultations with persons engaged in the devel-
 18 opment of a security countermeasure (as de-
 19 fined in section 319F–2 of the Public Health
 20 Service Act (42 U.S.C. 247d–6b)) (as amended
 21 by this Act), a qualified countermeasure (as de-
 22 fined in section 319F–1 of the Public Health
 23 Service Act (42 U.S.C. 247d–6a)) (as amended
 24 by this Act), or a qualified pandemic or epi-
 25 demic product (as defined in section 319F–3 of

1 the Public Health Service Act (42 U.S.C.
2 247d–6d)) for the purpose of the development,
3 manufacture, distribution, purchase, or storage
4 of a countermeasure or product. The Secretary
5 may convene such meeting or consultation at
6 the request of the Secretary of Homeland Secu-
7 rity, the Attorney General, the Chairman of the
8 Federal Trade Commission (referred to in this
9 section as the “Chairman”), or any interested
10 person, or upon initiation by the Secretary. The
11 Secretary shall give prior notice of any such
12 meeting or consultation, and the topics to be
13 discussed, to the Attorney General, the Chair-
14 man, and the Secretary of Homeland Security.

15 (B) MEETING AND CONSULTATION CONDI-
16 TIONS.—A meeting or consultation conducted
17 under subparagraph (A) shall—

18 (i) be chaired or, in the case of a con-
19 sultation, facilitated by the Secretary;

20 (ii) be open to persons involved in the
21 development, manufacture, distribution,
22 purchase, or storage of a countermeasure
23 or product, as determined by the Sec-
24 retary;

1 (iii) be open to the Attorney General,
2 the Secretary of Homeland Security, and
3 the Chairman;

4 (iv) be limited to discussions involving
5 covered activities; and

6 (v) be conducted in such manner as to
7 ensure that no national security, confiden-
8 tial commercial, or proprietary information
9 is disclosed outside the meeting or con-
10 sultation.

11 (C) LIMITATION.—The Secretary may not
12 require participants to disclose confidential
13 commercial or proprietary information.

14 (D) TRANSCRIPT.—The Secretary shall
15 maintain a complete verbatim transcript of each
16 meeting or consultation conducted under this
17 subsection, which shall not be disclosed under
18 section 552 of title 5, United States Code, un-
19 less such Secretary, in consultation with the At-
20 torney General and the Secretary of Homeland
21 Security, determines that disclosure would pose
22 no threat to national security. The determina-
23 tion regarding possible threats to national secu-
24 rity shall not be subject to judicial review.

25 (E) EXEMPTION.—

1 (i) IN GENERAL.—Subject to clause
2 (ii), it shall not be a violation of the anti-
3 trust laws for any person to participate in
4 a meeting or consultation conducted in ac-
5 cordance with this paragraph.

6 (ii) LIMITATION.—Clause (i) shall not
7 apply to any agreement or conduct that re-
8 sults from a meeting or consultation and
9 that is not covered by an exemption grant-
10 ed under paragraph (4).

11 (2) SUBMISSION OF WRITTEN AGREEMENTS.—
12 The Secretary shall submit each written agreement
13 regarding covered activities that is made pursuant to
14 meetings or consultations conducted under para-
15 graph (1) to the Attorney General and the Chairman
16 for consideration. In addition to the proposed agree-
17 ment itself, any submission shall include—

18 (A) an explanation of the intended purpose
19 of the agreement;

20 (B) a specific statement of the substance
21 of the agreement;

22 (C) a description of the methods that will
23 be utilized to achieve the objectives of the
24 agreement;

1 (D) an explanation of the necessity for a
 2 cooperative effort among the particular partici-
 3 pating persons to achieve the objectives of the
 4 agreement; and

5 (E) any other relevant information deter-
 6 mined necessary by the Attorney General, in
 7 consultation with the Chairman and the Sec-
 8 retary.

9 (3) EXEMPTION FOR CONDUCT UNDER AP-
 10 PROVED AGREEMENT.—It shall not be a violation of
 11 the antitrust laws for a person to engage in conduct
 12 in accordance with a written agreement to the extent
 13 that such agreement has been granted an exemption
 14 under paragraph (4), during the period for which
 15 the exemption is in effect.

16 (4) ACTION ON WRITTEN AGREEMENTS.—

17 (A) IN GENERAL.—The Attorney General,
 18 in consultation with the Chairman, shall grant,
 19 deny, grant in part and deny in part, or pro-
 20 pose modifications to an exemption request re-
 21 garding a written agreement submitted under
 22 paragraph (2), in a written statement to the
 23 Secretary, within 15 business days of the re-
 24 ceipt of such request. An exemption granted

1 under this paragraph shall take effect imme-
2 diately.

3 (B) EXTENSION.—The Attorney General
4 may extend the 15-day period referred to in
5 subparagraph (A) for an additional period of
6 not to exceed 10 business days.

7 (C) DETERMINATION.—An exemption shall
8 be granted regarding a written agreement sub-
9 mitted in accordance with paragraph (2) only to
10 the extent that the Attorney General, in con-
11 sultation with the Chairman and the Secretary,
12 finds that the conduct that will be exempted
13 will not have any substantial anticompetitive ef-
14 fect that is not reasonably necessary for ensur-
15 ing the availability of the countermeasure or
16 product involved.

17 (5) LIMITATION ON AND RENEWAL OF EXEMP-
18 TIONS.—An exemption granted under paragraph (4)
19 shall be limited to covered activities, and such ex-
20 emption shall be renewed (with modifications, as ap-
21 propriate, consistent with the finding described in
22 paragraph (4)(C)), on the date that is 3 years after
23 the date on which the exemption is granted unless
24 the Attorney General in consultation with the Chair-
25 man determines that the exemption should not be

1 renewed (with modifications, as appropriate) consid-
 2 ering the factors described in paragraph (4).

3 (6) AUTHORITY TO OBTAIN INFORMATION.—
 4 Consideration by the Attorney General for granting
 5 or renewing an exemption submitted under this sec-
 6 tion shall be considered an antitrust investigation for
 7 purposes of the Antitrust Civil Process Act (15
 8 U.S.C. 1311 et seq.).

9 (7) LIMITATION ON PARTIES.—The use of any
 10 information acquired under an agreement for which
 11 an exemption has been granted under paragraph (4),
 12 for any purpose other than specified in the exemp-
 13 tion, shall be subject to the antitrust laws and any
 14 other applicable laws.

15 (8) REPORT.—Not later than one year after the
 16 date of enactment of this Act and biannually there-
 17 after, the Attorney General and the Chairman shall
 18 report to Congress on the use of the exemption from
 19 the antitrust laws provided by this subsection.

20 (b) SUNSET.—The applicability of this section shall
 21 expire at the end of the 6-year period that begins on the
 22 date of enactment of this Act.

23 (c) DEFINITIONS.—In this section:

24 (1) ANTITRUST LAWS.—The term “antitrust
 25 laws”—

(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) COUNTERMEASURE OR PRODUCT.—The term “countermeasure or product” refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

(3) COVERED ACTIVITIES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term “covered activities” includes any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

(B) EXCEPTION.—The term “covered activities” shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection

1 (a)(4), the following activities involving 2 or
2 more persons:

3 (i) Exchanging information among
4 competitors relating to costs, profitability,
5 or distribution of any product, process, or
6 service if such information is not reason-
7 ably necessary to carry out covered activi-
8 ties—

9 (I) with respect to a counter-
10 measure or product regarding which
11 such meeting or consultation is being
12 conducted; or

13 (II) that are described in the
14 agreement as exempted.

15 (ii) Entering into any agreement or
16 engaging in any other conduct—

17 (I) to restrict or require the sale,
18 licensing, or sharing of inventions, de-
19 velopments, products, processes, or
20 services not developed through, pro-
21 duced by, or distributed or sold
22 through such covered activities; or

23 (II) to restrict or require partici-
24 pation, by any person participating in
25 such covered activities, in other re-

1 search and development activities, ex-
2 cept as reasonably necessary to pre-
3 vent the misappropriation of propri-
4 etary information contributed by any
5 person participating in such covered
6 activities or of the results of such cov-
7 ered activities.

8 (iii) Entering into any agreement or
9 engaging in any other conduct allocating a
10 market with a competitor that is not ex-
11 pressly exempted from the antitrust laws
12 under subsection (a)(4).

13 (iv) Exchanging information among
14 competitors relating to production (other
15 than production by such covered activities)
16 of a product, process, or service if such in-
17 formation is not reasonably necessary to
18 carry out such covered activities.

19 (v) Entering into any agreement or
20 engaging in any other conduct restricting,
21 requiring, or otherwise involving the pro-
22 duction of a product, process, or service
23 that is not expressly exempted from the
24 antitrust laws under subsection (a)(4).

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

SEC. 8. PROCUREMENT.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in the section heading, by inserting “**AND SECURITY COUNTERMEASURE PROCUREMENTS**” before the period; and

(2) in subsection (c)—

(A) in the subsection heading, by striking “BIOMEDICAL”;

(B) in paragraph (5)(B)(i), by striking “to meet the needs of the stockpile” and inserting “to meet the stockpile needs”;

1 (C) in paragraph (7)(B)—

2 (i) by striking the subparagraph head-
3 ing and all that follows through “Home-
4 land Security Secretary” and inserting the
5 following: “INTERAGENCY AGREEMENT;
6 COST.—The Homeland Security Sec-
7 retary”; and

8 (ii) by striking clause (ii);

9 (D) in paragraph (7)(C)(ii)—

10 (i) by amending clause (I) to read as
11 follows:

12 “(I) PAYMENT CONDITIONED ON
13 DELIVERY.—The contract shall pro-
14 vide that no payment may be made
15 until delivery of a portion, acceptable
16 to the Secretary, of the total number
17 of units contracted for, except that,
18 notwithstanding any other provision of
19 law, the contract may provide that, if
20 the Secretary determines (in the Sec-
21 retary’s discretion) that an advance
22 payment, partial payment for signifi-
23 cant milestones, or payment to in-
24 crease manufacturing capacity is nec-
25 essary to ensure success of a project,

1 the Secretary shall pay an amount,
2 not to exceed 10 percent of the con-
3 tract amount, in advance of delivery.
4 The Secretary shall, to the extent
5 practicable, make the determination of
6 advance payment at the same time as
7 the issuance of a solicitation. The con-
8 tract shall provide that such advance
9 payment is required to be repaid if
10 there is a failure to perform by the
11 vendor under the contract. The con-
12 tract may also provide for additional
13 advance payments of 5 percent each
14 for meeting the milestones specified in
15 such contract. Provided that the spec-
16 ified milestones are reached, these ad-
17 vanced payments of 5 percent shall
18 not be required to be repaid. Nothing
19 in this subclause shall be construed as
20 affecting the rights of vendors under
21 provisions of law or regulation (in-
22 cluding the Federal Acquisition Regu-
23 lation) relating to the termination of
24 contracts for the convenience of the
25 Government.”; and

1 (ii) by adding at the end the fol-
2 lowing:

3 “(VII) SALES EXCLUSIVITY.—

4 The contract may provide that the
5 vendor is the exclusive supplier of the
6 product to the Federal Government
7 for a specified period of time, not to
8 exceed the term of the contract, on
9 the condition that the vendor is able
10 to satisfy the needs of the Govern-
11 ment. During the agreed period of
12 sales exclusivity, the vendor shall not
13 assign its rights of sales exclusivity to
14 another entity or entities without ap-
15 proval by the Secretary. Such a sales
16 exclusivity provision in such a con-
17 tract shall constitute a valid basis for
18 a sole source procurement under sec-
19 tion 303(c)(1) of the Federal Property
20 and Administrative Services Act of
21 1949 (41 U.S.C. 253(c)(1)).

22 “(VIII) SURGE CAPACITY.—The

23 contract may provide that the vendor
24 establish domestic manufacturing ca-
25 pacity of the product to ensure that

1 additional production of the product is
2 available in the event that the Sec-
3 retary determines that there is a need
4 to quickly purchase additional quan-
5 tities of the product. Such contract
6 may provide a fee to the vendor for
7 establishing and maintaining such ca-
8 pacity in excess of the initial require-
9 ment for the purchase of the product.
10 Additionally, the cost of maintaining
11 the domestic manufacturing capacity
12 shall be an allowable and allocable di-
13 rect cost of the contract.

14 “(IX) CONTRACT TERMS.—The
15 Secretary, in any contract for procure-
16 ment under this section, may speci-
17 fy—

18 “(aa) the dosing and admin-
19 istration requirements for coun-
20 termeasures to be developed and
21 procured;

22 “(bb) the amount of funding
23 that will be dedicated by the Sec-
24 retary for development and ac-

1 quisition of the countermeasure;
2 and

3 “(cc) the specifications the
4 countermeasure must meet to
5 qualify for procurement under a
6 contract under this section.”; and

7 (E) in paragraph (8)(A), by adding at the
8 end the following: “Such agreements may allow
9 other executive agencies to order qualified and
10 security countermeasures under procurement
11 contracts or other agreements established by
12 the Secretary. Such ordering process (including
13 transfers of appropriated funds between an
14 agency and the Department of Health and
15 Human Services as reimbursements for such or-
16 ders for countermeasures) may be conducted
17 under the authority of section 1535 of title 31,
18 United States Code, except that all such orders
19 shall be processed under the terms established
20 under this section for the procurement of coun-
21 termeasures.”.

22 **SEC. 9. RULE OF CONSTRUCTION.**

23 Nothing in this Act, or any amendment made by this
24 Act, shall be construed to affect any law that applies to
25 the National Vaccine Injury Compensation Program under

1 title XXI of the Public Health Service Act (42 U.S.C.
2 300aa–1 et seq.), including such laws regarding—

3 (1) whether claims may be filed or compensa-
4 tion may be paid for a vaccine-related injury or
5 death under such Program;

6 (2) claims pending under such Program; and

7 (3) any petitions, cases, or other proceedings
8 before the United States Court of Federal Claims
9 pursuant to such title.

○